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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/220,275	12/23/1998	STEPHEN H. FRIEND	9301-039-999	3713
20583	7590	11/19/2003	EXAMINER	
PENNIE AND EDMONDS 1155 AVENUE OF THE AMERICAS NEW YORK, NY 100362711			MARSCHEL, ARDIN H	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/220,275	FRIEND ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ardin Marschel	1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 58-64 and 70-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58-64 and 70-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicants' arguments, filed 8/25/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **VAGUENESS AND INDEFINITENESS**

Claims 58-64 and 70-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained and reiterated from the previous office action, mailed 2/24/03. Applicants argue that the phrase "one or more experimental values" has been misinterpreted and that such values are defined in the specification at page 34, lines 29-32. Consideration of said page 34 citation reveals that experimental variables are exemplified as argued by cell culture density etc. but that therein is no clear and concise definition of what is meant by "desired values". Again as set forth in this rejection previously the meaning of "desired values" is at best an assumption, as no definition has been pointed to, and therefore not clear and concise as required under 35 U.S.C. § 112, second paragraph.

### **PRIOR ART**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1631

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 58-61 and 71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felder et al. (P/N 6,232,066) alone; or, alternatively, taken in view of Singer et al. (P/N 5,866,331).

This rejection is maintained and reiterated from the previous office action, mailed 2/24/03. Applicants firstly admit that Felder et al. teaches control probe practice that are not expected to be modulated by perturbing agents and then confusingly then respectfully point out that neither Felder et al. nor Singer et al. teach control probe experiments. Thus, this argument based on both an admission of something which is then argued as not in the references is non-persuasive due to conflicting fact patterns therein. Also, in response the practice of control probe experiments were previously set forth in the combination of references and have not been negated by applicants' confusing argument on this point.

Applicants then argue that the rejection is based on a misinterpretation of the claim wording and point to the phrase "one or more experimental values". Such values are not seen as having been misinterpreted and are noted also as being briefly

discussed above regarding the corresponding phrase "desired values" which is significant in this response. Therefore, continuing to argue a definition of such values without clearly and concisely setting forth in the claims what is meant by "desired values" leaves this vague and indefinite phrase up to various interpretations including the control experiment determinations of responses in various control experiments as set forth in the basis of this rejection. Applicants then argue that background levels measured in without a sample are not measurements of cellular constituents. In response such background measurements are directed to determining what such background contributes to measurements of changes etc. in cellular constituents and therefore are included experimentally in biological response profile measurements contrary to this argument of applicants.

Applicants then argue a reiteration of a previously set forth argument. This argument has been previously responded to as being non-persuasive and applicants have not pointed to any aspect of the previous response as what should be reconsidered. Therefore, the previous response is reiterated and maintained.

Applicants then summarize the instant invention and no argument is seen therein to respond to except in the sentence bridging pages 11 and 12 of REMARKS, filed 8/25/03. This sentence apparently summarizes previous arguments that have been responded to already as being non-persuasive and is equally therefore non-persuasive here regarding such a summary.

In the first full paragraph on page 12 of the REMARKS, filed 8/25/03, applicants seem to be submitting a definition of what is meant by "desired values". Such an added

Art Unit: 1631

definition fails to clarify the instant disclosure as filed and therefore cannot overcome this rejection which is based at least partially on the vague and indefinite claim language which has been set forth from the actual disclosure as filed. Notwithstanding the above noted submission of a definition of "desired values", the argument in said paragraph is still non-persuasive in that it argues that background values are not changes in cellular constituents and therefore not meant to be deviations in experimental variables as in the claims. In response, background values are well known to be included in cellular constituent measurements and as such are included in any pattern of measurements of changes in cellular constituents. Such measurements are clearly set forth in the claims, for example, in claim 58, line 5, and then "subtracted" in line 7 of instant claim 58. This is set forth in the combination of references and clearly supports this rejection.

Singer et al. is briefly discussed on page 12 of the REMARKS, filed 8/25/03, but without specifically arguing any of the basis for this reference in the rejection and therefore is non-persuasive as not being directed to the basis for the rejection as previously set forth.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

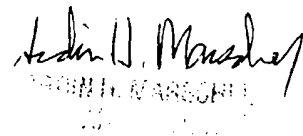
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

November 14, 2003



ARDIN H. MARSCHEL